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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,789

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EXAMINER

FLORY, CHRISTOPHER A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,789	Applicant(s) HETTRICK ET AL.	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/18/08 have been fully considered but they are not persuasive. Claims 1-3, 5-14, 16-26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Zhou'856. Claim 26 stands rejected under 35 U.S.C. 102(e) as anticipated by Zhou'859 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhou'859 in view of Bolhuis'273. Claims 1-3, 5-7, 12-14, 16-18 and 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra'459. Claim 26 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra'459 in view of Bolhuis'273.
2. Regarding Applicant's argument that Zhou'856 fails to teach adjusting parameters in response to detecting an increased frequency of first events, Figure 6 clearly shows monitoring of intervals as a measure of heart rate (710), and determines arrhythmia based on a heart rate a step 712 (i.e. increased number of beats or increased rate frequency), upon which determination therapy is delivered (715).
3. Regarding Applicant's arguments that Mehra'459 teaches sensing events while the therapy is already being delivered, it is noted that Figures 10-12 show a method by which therapy is selectively turned on and off, such that sensing can occur prior to the delivery of a second round of therapy or a continued therapy, but with updated parameters. E.g. Figure 12 shows monitoring/sensing at step 908, adjusting parameters at step 914, and then recursively administering therapy with the new altered-parameter driven therapy after step 916.

4. Regarding Applicant's argument directed to the inherency of an increase in PAC frequency requiring a shorter coupling interval, it is noted that the inherency is not necessary to maintain proper motivation of combining the references to meet the claim limitations.

Election/Restrictions

5. Newly submitted claim 27 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention of claim 27 is distinct from the inventions of claims 1-3, 5-14 and 16-26 because the invention of claims 27 requires the delivered therapy to be atrial overdrive pacing, the detected signal to be an atrial rhythm, and the second event an atrial tachycardia. The other claims are not limited in any of these variables, as the therapy could be delivered to a ventricle, a combination of atria and ventricles, or in the broad sense of the independent claims are not even required to be related to a cardiac event. Similarly, the therapy, whether delivered to an atrium or not, is not required to be overdrive pacing, but could be a different form of pacing, or resynchronization therapy, or defibrillation. Finally, the detected signal could be a ventricular signal or a variable related to respiration, body impedance, etc, with the second event being either outside the atria or defined by something other than a tachycardia (e.g. bradycardia). See MPEP § 806.05(j).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 27 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-14, 16-26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Zhou et al. (US 7,027,856, hereinafter Zhou'856).

Regarding claims 1, 3, 9, 12, 14, 20 and 23-25, Zhou'856 discloses an implantable medical device and method comprising an electrode means for sensing a plurality of cardiac events prior to delivering a therapy (abstract; Fig. 1, electrodes 17-23); a processor means for detecting a sudden increase in the frequency of first events corresponding to triggering an onset of a different second event different from the first (column 2, lines 60-67; column 9, lines 22-28 and 58-63); means for adjusting rate or duration of therapy delivery in response to detected increase in frequency (ibid.; abstract); means for initiating therapy using the updated parameters (e.g. Fig. 5, step 535; Fig. 6, step 715) wherein the increase in frequency is determined over a time period of up to approximately one minute (column 2, lines 1-4); and means for

determining, in response to an increase in frequency of the first events not being detected and for which therapy has not been delivered, whether a predetermined number of second events have occurred, and automatically adjusting parameters associated with the first events in response to the predetermined number of second events occurring (column 12, lines 1-19, Figs. 6-8).

Regarding the newly amended clause that the sensing occur prior to delivering therapy, it is noted that Zhou'856 discloses a method of sensing, using the sensed data to adjust parameters, and then deliver therapy. Therefore, sensing occurs prior to delivering therapy. See, for example, Fig. 6, wherein sensing occurs at step 710 prior to delivery of therapy at step 715. Regarding the first and second events being different, it is noted that the first event being sensed is the disclosed interval relating to heart rate, and the second event is the detection of arrhythmia as previously explained. Regarding initiating therapy using the adjusted parameters, Fig. 7 shows a path wherein parameters are adjusted at step 30 and then used to deliver therapy at step 752, with parameters being readjusted at step 770 if necessary.

Regarding claims 2, 5, 7, 11, 13, 16, 18 and 22, Zhou'856 discloses that the first events correspond to a number of premature atrial contractions occurring in a predetermined time window (column 12, lines 1-19).

Regarding claims 6, 8, 10, 17, 19 and 21, and further regarding claim 7 and 18, Zhou'859 is considered to disclose means for determining if the second event is detected subsequent to or during delivery of therapy and increasing therapy rate in response to the second event (Figs. 6-8).

Claim Rejections - 35 USC § 102/103

8. Claim 26 stands rejected under 35 U.S.C. 102(e) as anticipated by Zhou'859 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhou'859 in view of Van Bolhuis et al. (US 2004/0215273, hereinafter Bolhuis'273).

Regarding claim 26, Zhou'859 is considered to disclose detection of increase in frequency of the first event by determining shortening coupling intervals insomuch as the coupling interval is also commonly known as the P-P interval (column 1, lines 33-36; column 3, lines 8-19; column 7, line 65 through column 8, line 3; column 10, lines 14-23). Alternatively, in the same field of endeavor, Bolhuis'273 teaches that the length of a PAC coupling interval identifies whether the PAC is likely to trigger onset of an arrhythmia episode, and therefore allows to distinguish between PAC types and prevent delivery of unnecessary therapy (paragraphs [5], [21], [32]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Mehra'459 with measuring the length of the PAC coupling interval as taught by Bolhuis'273 to provide Mehra'459 with the same advantage of classifying PACs so as not to deliver unnecessary therapies. It is noted that an increase in PAC frequency would inherently require a shorter coupling interval, since the coupling interval is inherently the characteristic that sets the inter-PAC duration.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 5-7, 12-14, 16-18 and 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al (U.S. 6185459, hereinafter Mehra'459).

Referring to claims 1-2, 12, 13 and 23-25, Mehra'459 teach a pacemaker that delivers tachyarrhythmia prevention therapy for an extended period of time (see Abstract). The pacemaker can employ a metric to determine if therapy is successful. The metric measured can be the frequency of occurrence of PACs, and further may be a defined range of PACs per hour, determined by the physician to represent an acceptable range of occurrences of PACs. The aggressiveness of the atrial arrhythmia prevention pacing modality employed may be increased in response to the number of occurrences of PACs being in excess of the defined endpoint range (see column 4, lines 5-12 and lines 30-38).

Further regarding claims 1, 12 and 23-25, Mehra'459 is considered to disclose a means for detecting a sudden increase in the frequency of PACs insomuch as a change over a two-day period can be considered "sudden" in comparison to trends measured over weeks or months. Alternatively, even though the device of Mehra'459 is disclosed to monitor trends over certain periods of time with the examples of days, weeks or months, this does not preclude monitoring over shorter periods, also able to be

considered of a sudden nature. Further, the Mehra'459 inherently must measure each heartbeat or PAC in order to trend such a statistic over a longer period of time, and therefore inherently detects changes on a beat-to-beat basis, which qualifies as a sudden increase.

Still further regarding claims 1, 12 and 23-25, Mehra'459 inherently detects increases over a period of up to approximately one minute, since the Mehra'459 device can detect increases of periods longer than that, e.g. up to a period of days, weeks or months. Detecting increase over a two-day period inherently includes detecting increases over a time period of approximately one minute. Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention to detect increases in first event frequency over a time period of one minute, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. In this case, it would be obvious to measure increase over time periods of one minute when the intention is to update the delivered therapy on a more frequent basis.

Still further regarding claims 1, 12 and 23-25, it is noted that as written the independent claims do not require the first and second events to be from separate event classes, and could therefore both refer to the same type of event, such as a tachyarrhythmia, occurring multiple times. Given this interpretation, Mehra'459 clearly discloses the argued limitation, since the metric, upon not sensing a first

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tachyarrhythmic event and therefore not delivering a therapy goes into a reiterative process until a successful tachyarrhythmic (second) event is sensed, at which time parameters are adjusted and therapy is delivered, wherein the predetermined number of second events is one

Regarding claims 3 and 14, Mehra'459 teach that in response to an increase in PACs/day, the rate of the therapy may be increased (see column 21, lines 65-67 and column 22, lines 1-10). With reference to claims 4-5 and 15-16, Mehra'459 teach the device described above and further disclose that certain endpoints such as PACs/day and AF/day may be defined for a 24-hour period. Due to one or both of the PAC/day and AF/day values exceeding the defined acceptable ranges, the pacing parameters are adjusted to be more aggressive by either increasing or decreasing the rate. During a new 24-hour period, data is collected with the newly adjusted endpoints (see column 21, lines 57-67 and column 22, lines 1-15).

With regards to claims 6-7 and 17-18, Mehra'459 disclose that the metric used to optimize the parameters of the arrhythmia prevention pacing modality may also be employed to disable the arrhythmia prevention pacing modality or to trigger the switch to an alternative pacing prevention modality (see column 4, lines 45-51). While not stated explicitly, it is inherent that arrhythmia detection subsequent to therapy is employed since the therapy is arrhythmia prevention pacing modality, and detecting an arrhythmia would prove the pacing to be ineffective.

11. Claim 26 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra'459 in view of Bolhuis'273.

Regarding claim 25, Mehra'459 discloses the invention substantially as claimed including detecting that there is an increase in the frequency of first events, but does not expressly disclose that the frequency increase is made by determining whether a coupling interval of a most recent first event is shorter than that of a previous first event. In the same field of endeavor, Bolhuis'273 teaches that the length of a PAC coupling interval identifies whether the PAC is likely to trigger onset of an arrhythmia episode, and therefore allows to distinguish between PAC types and prevent delivery of unnecessary therapy (paragraphs [5], [21], [32]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Mehra'459 with measuring the length of the PAC coupling interval as taught by Bolhuis'273 to provide Mehra'459 with the same advantage of classifying PACs so as not to deliver unnecessary therapies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

20 May 2008

/George Manuel/
Primary Examiner